Application No.: 09/613,707

Docket No.: HO-P02004US0

### REMARKS

At this time, Applicants wish to thank the Examiner for her time during the telephonic interview of January 28, 2003. During the telephonic interview, all pending rejections and objections were discussed. More specifically, the scope of the claims were discussed in view of the prior art. Applicants indicated that the scope of the claims covered cell lines having a given ATCC accession number and that these specific cell lines were not taught nor suggested by Dran et al. In view of this explanation, the Examiner indicated that the recitation of the ATCC accession number obviated the rejection.

Yet further during a second telephonic interview on January 30, 2003, Applicants discussed with the Examiner adding all four cell lines having ATCC accession numbers into the claims. Applicants indicated that shifting the scope of the claims from one cell line to four cell lines would result in no additional work or expanse for the Examiner and if anything may reduce work by simplifying the issues, such as additional applications for each cell line. See MPEP § 819.01. The Examiner agreed to review claims of the four cell lines.

#### A. Status of Application

Claims 5, 7, 8 and 11 are pending in this application. Applicants have amended claims 5, 7, 8 and 11 without prejudice and acquiescence. Support for the amendments can be found in the original claims as filed and in the Specification on page 4, lines 19-24 and page 5, lines 1-5. Applicants have enclosed as Appendix A a marked version of the claims illustrating the amendments contained herein. For the convenience of the Examiner, Applicants have also enclosed in Appendix B a copy of all pending claims containing the amendments herein. Applicants assert that no new matter is added.

The issues outstanding in this application are as follows:

- The specification has been objected as the Office Action alleges that Applicants have not meet the conditions of the Budapest Treaty.
- Claims 5 and 11 have been rejected under 35 U.S.C. §103(c), which the Office Action alleges that the claimed subject matter is obvious by Dran et al.

Applicants respectfully traverse the outstanding rejections and objections, and

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Applicants respectfully request reconsideration and withdrawal thereof in light of the amendments and remarks contained herein.

#### B. The Specification meets all requirements.

The Action has objected to the Specification because the Office Action alleges that Applicants have not meet the conditions of the Budapest Treaty. Applicants traverse.

Applicants enclose herewith notification from the ATCC indicating the deposition of the biological material. Yet further, in the previous response filed on September 18, 2002, Applicants amended the Specification to recite the name and address of the depository and the dates of the deposit. Still further, Applicants assert that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent.

Thus, Applicants assert that all requirements have been meet under the Budapest Treaty and under 37 CFR 1.808 and respectfully request withdrawal of the objection.

#### C. Claims 5 and 11 are not anticipated.

Claims 5 and 11 have been rejected under U.S.C. § 103(c), which the Office Action alleges that the claimed subject matter is obvious by Duran et al. Applicants respectfully traverse.

Applicants assert that there is a distinct difference between a primary cell culture and the cell line of the present invention. The primary cell culture of Dran et al., has a lifespan of about two weeks. The cell lines of the present invention are immortal.

However, in order to advance the prosecution of the present application, Applicants have amended claims 5 and 11 to recite the ATCC accession number of the cell lines of the present invention. During the telephonic interview, the Examiner indicated that the recitation of the ATCC accession number of the cell lines would obviate the rejection, thus, in light of this amendment, Applicants respectfully request withdrawal of the rejection.

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## **CONCLUSION**

Claims 5, 7, 8 and 11 are pending in this application. Claims 5, 7, 8 and 11 have been have been amended without prejudice and acquiescence.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If there are any outstanding issues, Applicants respectfully request that the undersigned be contact so that these issues may be resolved quickly and this application can proceed to allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. 10020885 from which the undersigned is authorized to draw.

Dated: February 13, 2003

Respectfully submitted,

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# Appendix A Version With Markings to Show Changes Made

(Amended Twice) A non transgenic mouse mammary adenocarcinoma cell line 5. derived from a murine progestin independent C7-HI tumor, wherein the cell line expresses estrogen and progesterone receptors and the cell line is selected from the group consisting of MC4-L1 (ATCC# PTA-889), MC4-L3 (ATCC# PTA-891), MC4-L2 (ATCC# PTA-892) and MC7-L1 (ATCC # PTA-890)MC7-L1 (ATCC # PTA-890).

- (Amended) A non-transgenic mouse mammary adenocarcinoma cell line system for 7. testing the activity of a hormone, an anti-hormone, a pharmacological compound and an environmental agent, wherein the system comprises a cell line selected from the group consisting of a MC4-L1 (ATCC# PTA-889), MC4-L3 (ATCC# PTA-891), MC4-L2 (ATCC# PTA-892) and MC7-L1 (ATCC # PTA-890) cell line. MC7-L1 cell line.
- (Amended) An in vitro method for testing the activity of a hormone, an anti-8. hormone, a pharmacological compound or an environmental agent, comprising the steps of:

cultivating a cell line system, wherein the cell line system comprises a cell line selected from the group consisting of MC4-L1 (ATCC# PTA-889), MC4-L3 (ATCC# PTA-891), MC4-L2 (ATCC# PTA-892) and MC7-L1 (ATCC # PTA-890); a MC7-L1 cell line derived from a murine progestin-independent C7-HI tumor, wherein the cell line expresses estrogen and progesterone receptors;

exposing the cell line system to the hormone, the anti-hormone, the pharmacological compound, or the environmental agent; and quantifying cell proliferation.

(Amended Twice) A kit for determining the effect of a hormone, anti-hormone, 11. pharmacological compounds and environmental agents, wherein the kit comprises an aliquot of a cell line selected from the group consisting of MC4-L1 (ATCC# PTA-889), MC4-L3

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(ATCC# PTA-891), MC4-L2 (ATCC# PTA-892) and MC7-L1 (ATCC # PTA-890)a MC7-

L1 cell line (ATCC# PTA-890), and a method for evaluating the proliferation of cells.

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Appendix B
Claims Pending as of February 13, 2003

5. (Amended Twice) A non transgenic mouse mammary adenocarcinoma cell line-, wherein the cell line is selected from the group consisting of MC4-L1 (ATCC# PTA-889), MC4-L3 (ATCC# PTA-891), MC4-L2 (ATCC# PTA-892) and MC7-L1 (ATCC # PTA-890).

- 7. (Amended) A non-transgenic mouse mammary adenocarcinoma cell line system for testing the activity of a hormone, an anti-hormone, a pharmacological compound and an environmental agent, wherein the system comprises a cell line selected from the group consisting of MC4-L1 (ATCC# PTA-889), MC4-L3 (ATCC# PTA-891), MC4-L2 (ATCC# PTA-892) and MC7-L1 (ATCC # PTA-890) cell line..
- 8. (Amended) An *in vitro* method for testing the activity of a hormone, an antihormone, a pharmacological compound or an environmental agent, comprising the steps of:

cultivating a cell line system, wherein the cell line system comprises a cell line selected from the group consisting of MC4-L1 (ATCC# PTA-889), MC4-L3 (ATCC# PTA-891), MC4-L2 (ATCC# PTA-892) and MC7-L1 (ATCC # PTA-890);

exposing the cell line system to the hormone, the anti-hormone, the pharmacological compound, or the environmental agent; and quantifying cell proliferation.

11. (Amended Twice) A kit for determining the effect of a hormone, anti-hormone, pharmacological compounds and environmental agents, wherein the kit comprises an aliquot of a cell line selected from the group consisting of MC4-L1 (ATCC# PTA-889), MC4-L3 (ATCC# PTA-891), MC4-L2 (ATCC# PTA-892) and MC7-L1 (ATCC # PTA-890) and a method for evaluating the proliferation of cells.